HOW TO GET INFORMATION ON CHEMICALS FOR RISK ASSESSMENT – THE EU-WHITEBOOK AND DIRECTIVE 98/24/EC.

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A. The Commission's White Paper on Chemicals

The European Commission adopted a "White Paper" setting out the strategy for a new Chemicals Policy on February 13th, 2001. The Commission proposes converting the current dual system for "existing" and "new" chemicals and their respective testing requirements into a single efficient and coherent system for dealing with the majority of chemicals. It proposes that, in future, the responsibility for testing and risk assessment of chemicals should be placed on producers and importers. The national authorities will be then called in to evaluate the data provided and determine future testing strategies. Increased responsibility will also pass to users in the manufacturing chain i.e. formulators and downstream users, who will supply data on the particular uses they make of the chemicals.
This new single system for assessing both existing and new chemicals will be known as the **REACH** system (**R**egistration, **E**valuation, and **A**uthorisation of **C**hemicals) and comprises of three elements:

- **Registration:**
  All substances produced or imported at quantities greater than 1 ton (per producer/importer per year) will have to be registered (ca. 30,000 chemicals) with different basic information submitted dependent on the quantities (1 ton, 10 ton, 100 ton, 1000 ton) submitted to a central registration body and central database. High volume chemicals will have to be registered first. Registering companies will have to submit a provisional risk assessment.

- **Evaluation:**
  All substances above 100 ton (as above) and problematic substances (those of concern) which are at lower tonnages will have to be evaluated by member state authorities.

- **Authorisation** (Restriction step):
  Substances classified as carcinogenic/mutagenic/toxic for reproduction (C/M/R) categories 1 or 2 and the Persistent Organic Pollutants (POPs) will be subject to authorisation. Such substances will require justification for their continued use by industry within a specific time frame, otherwise the substance will be restricted.

B. Comments and proposals for workers protection

1. General involvement of occupational health and safety

- Occupational exposure is not sufficiently taken aboard The white paper does not deal explicitly with health protection of employees, neither does it give a full analysis of the relation between the different legislative domains and instruments (e.g. health based recommended limit values), and the necessary information needed for a full risk assessment of occupational risks. The occupational domain in the white paper is implicitly incorporated in “human health”. The differences in risks, situations and susceptibility between the general public and employees are not made explicate. The white paper analysis and foreseen instruments do not take sufficient account of the specifics of occupational exposure.
- The central idea of the White Paper – that “new” chemicals and “existing” chemicals should be dealt with in the same way within the REACH system – is an acceptable approach. Setting a clear timetable for completing the work is welcomed. Shifting the burden from public authorities to industry, at least to a large extent, is correct and can be supported. However in doing so too many compromises have been made with respect to the required data sets which are related to specific production levels. It is not clear how adequate protection of workers can be guaranteed under these conditions, as set out in greater detail below.

2. Central focus: Testing requirements.

- One of the purposes of the white paper is to limit in vivo testing. However, risk assessment with respect to occupational health risks can at present not be done without appropriate in vivo test results. Protection of workers should be given higher priority than limitation of in vivo testing.

In parallel the Commission should set up a programme to develop in vitro testing methods which can substitute in vivo testing methods in the future.

- Every employer is obliged to take all the necessary measures to ensure health protection for his workers. In order to comply with this requirement he needs access to instruments and data enabling him to make a proper risk assessment covering all possible risks related to the actual use of chemicals at the workplace. This will only be possible if the requirements foreseen in the white paper guarantee that this information is available. It is not acceptable that as a result of insufficient resources to generate all this information the unknown risks will be placed on workers.

- Testing requirements start with substances which are produced in a quantity of 1 ton per year per producer/importer. The fact that the tonnage levels are fixed at level of the individual producer/importer can imply that the total tonnage on the European market for a single substance can be significantly much higher.

- The new system would apply to all chemicals the level from which testing is required is raised by a factor 10, compared to new chemicals, and leading to a situation in which for 80% of all used chemicals test requirements will not exist. Health protection of workers using these 80% chemicals will remain rudimentary, which is not acceptable.

- Test requirements below the level of the base set for new substances (see annex VII A of directive 67/548/EEC) do not allow any sound assessment of the toxicological and environmental properties of a substance, which are the basis for e.g. deriving occupational exposure limit values. Under the proposed system, this base set would only be necessary for substances produced/imported in equal amounts or above 10 ton/year. The estimated number of substances produced/imported above 10 ton/year is 10.000.

As a consequence, two thirds (20.000) of all existing substances envisaged to be tested at all (above 1 ton/year are around 30.000), will be able to be marketed and used on the basis of a data set, which doesn't allow any adequate risk assessment from the point of view of workers protection, in particular not for establishing occupational exposure limits (OEL) which are normally based on

sub-chronic and chronic inhalation studies. Therefore on a case by case basis sub-chronic inhalation studies should be requested for chemicals below 100 ton/year.

3. Central focus: risk assessment

- "Waiving of testing" is envisaged under certain circumstances, amongst others on the basis of certain exposure scenarios, for example "testing requirements for strictly controlled and rigorously contained intermediates should be reduced". This exposure scenarios have to be delivered by industry, the questions remains on which data such decision will be based at all, if – as stressed and mentioned several times in the White paper – those data are hardly available. An agreed scenario "closed system" for site limited intermediates is described in 28th adaptation of directive 67/548/EEC.

- Another criticism concerns the way the Commission intends to collect data for the assessment of chemicals below a certain tonnage level (100 ton/year) which will only be available if the substance is produced at quantities above this specific tonnage level. On several occasions, the Commission stated that hazardous substances, even if they are produced below a certain tonnage level, would also become subject to the different stages of the REACH system if there is any information / data which causes concern. However the crucial point is that below 10 ton/year data causing concern with respect to subacute toxicity are not produced on a regular basis. Hence the chance to detect a 'black sheep' between the remaining substances of the lower tonnage group is minute.

- Chemical substances are evaluated and assessed, notably in DG ENVIRONMENT (existing substances and biocides) and DG SANCO (plant protection products). Furthermore, both DGs develop Technical Guidance Documents on assessment of chemical substances. These projects look in different detail at the working environment and input from DG EMPLOYMENT and SCOEL is urgently required. The concept to derive NOEL in the risk assessment and the concepts for an OEL should be compatible.

- After finalization of the Risk Assessment Reports risk reduction should be immediately initiated by the Commission. Up to date in regulation 793/93/EEC most concerns identified in the risk

assessments were in the working environment. An input of DG EMPLOYMENT on the scope and procedure for risk reduction for the workers is very much needed (including OEL setting procedures).

4. Focus: authorisation

- The authorisation, if the procedure is not bureaucratic, will lead to an essential improvement of the working conditions in Europe.
- The white paper does not contain an analysis of the relationship to the current directives on chemicals in the field of occupational safety and health as well as of its consequences. This especially applies for carcinogens (banned for private consumer by 76/769/EEC, but only substitution requirement for workers in 90/394/EEC) and authorised chemicals like biocides and pesticides.
- Furthermore it does not cover new problems arising from highly sensitising substances or highly chronic toxic substances.

  Reasoning:

  Sensitising substances represent a serious problem for human health:

  - Allergic reactions belong to the most frequent causes of occupational diseases.
  - Respiratory tract sensitisation is a life threatening disease.
  - Respiratory tract sensitisation can be caused by a single high exposure.
  - Skin sensitisation is a rather troublesome and long lasting disease.
  - Because of highly variable sensitivity of humans no safe level of exposure can be determined.
  - Protective measures are ineffective (accidental release of respiratory sensitisers) or not applicable (gloves with certain working operations).
  - As a cure is not possible exposure has to be avoided.
  - Allergy costs are estimated at € 29 billion/year in Europe (White Paper).

  Chronic toxic substances represent a serious problem for human health:

  - Disease can be life threatening.
  - Damage remains undetected until a certain degree of damage has occurred.
  - Low levels of exposure cause damage.
  - Exposure is merely controlled in small and medium sized enterprises.

It is important to stress that the hazardous properties that lead to authorisation need to be identified via appropriate testing strategies to trigger the authorisation procedure. The relation between OSH legislation and the authorisation needs to be clarified.

This paper was compiled by using ideas from the Ad-hoc-group on chemicals (advising council, Luxembourg) and the Federal Agency on Occupational Safety (Dr. R. Arndt, Dortmund).